510(k) Summary according to 807.92(c)

MAY 13 2010

Date: April 9, 2010
Contact: Tim Lusby
Amendia™, LLC
1155 Allgood Road, Suite 6
Marietta, GA 30062
770-874-0935

Trade Name: Diamond Anterior Cervical Plate System
Product Class: Class II
Classification: 888.3060
Product Codes: KWQ
Panel Code: 87 Orthopedics

Indications for Use: The Diamond Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spondylolisthesis
- Spinal Stenosis.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

Device Description: The Diamond Anterior Cervical Plate System is made of a medical grade titanium alloy and Nitinol, and consists of plates and screws of various lengths to accommodate single or multilevel fusions and variations in patients' anatomy. One level plates range from 22mm to 34mm. Two level plates range from 36mm to 54mm. Three level plates range from 53mm to 77mm. Four level plates range from 68mm to 92mm. All plates are 18mm wide and have an average thickness of 2.5mm. The screws range in sizes from 12 mm to 18 mm and come in diameters of 4.0mm and 4.3mm.

Predicate Device(s): Predicate devices previously cleared by FDA include the X-Spine ACP (K041469), the Synthes CSLP (K000536) and the Medtronic Orion Anterior Cervical Plate System K042499).

Performance Testing: The Diamond Anterior Cervical Plate System was mechanically tested using ASTM 1717. Tests included were: Static Compression Bending, Static Torsion, Static Tension Bending, and Dynamic Compression Bending. The pre-clinical testing performed indicated that the Diamond Anterior Cervical Plate is substantially equivalent to the predicate devices and is adequate for the intended use.

Comparison with Predicate: The Diamond Anterior Cervical Plate System and Medtronic Orion Anterior Cervical Plating System are both composed of Titanium Alloy and Nitinol. Synthes Spine CSLP and X-Spine ACT system are both composed of Titanium Alloy. The dimensions of Synthes Spine CSLP variable plate is 18mm wide and 2.5mm thick which is roughly equivalent to the Diamond Anterior Cervical Plate which is 18mm wide and has an average thickness of 2.5mm. The Diamond Anterior Cervical Plate System is also provided in the same lengths as the X-Spine ACT system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Amendia™, LLC
% Mr. Tim Lusby
1155 Allgood Road, Suite 6
Marietta, Georgia 30062

Re: K100265
Trade/Device Name: Diamond Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 09, 2010
Received: April 12, 2010

Dear Mr. Lusby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement of Indications for Use

510(k) Number (if known): K100265

Indications for Use:
The Diamond Anterior Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100265